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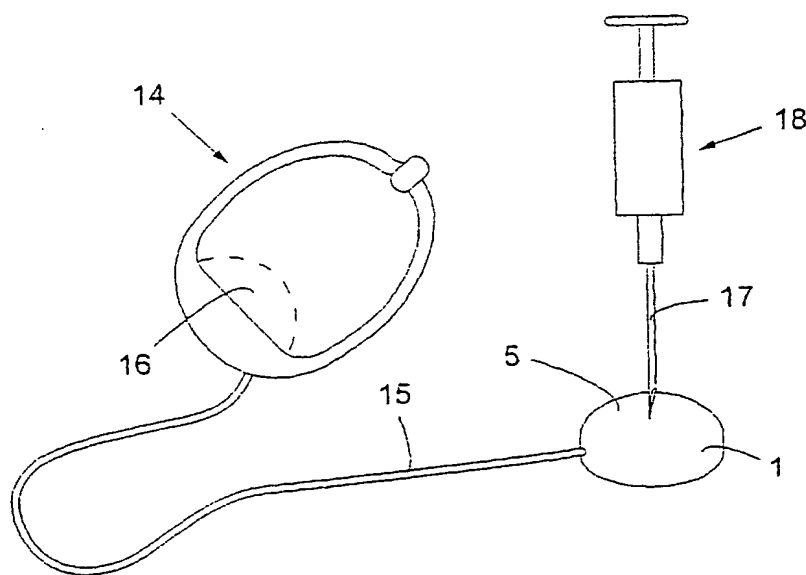
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- (71) Applicant (for all designated States except US): POTENCIA MEDICAL AG [CH/CH]; Zugerstrasse 74, CH-6341 Baar (CH).
- (72) Inventor: and
- (75) Inventor/Applicant (for US only): FORSELL, Peter [SE/CH]; Aegeristrasse 66, CH-6300 Zug (CH).
- (74) Agent: HAGSTRÖM, Leif; Bergensråhle & Lindvall AB, P.O. Box 17704, S-118 93 Stockholm (SE).
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(54) Title: IMPLANTABLE PUMP FOR OPERATION OF HYDRAULIC IMPLANT



(57) **Abstract:** An implantable pump (1) for pumping fluid to or from a hydraulic surgical implant (14) inside a human's or an animal's body comprises a wall (2) forming a chamber (3) for the fluid, the wall including a base plate (4) and a membrane (5), which is displaceable relative to the base plate to change the volume of the chamber (3) to pump the fluid between the chamber and the surgical implant. The membrane (5) is penetrable by an injection needle (17) to add hydraulic fluid to or withdraw hydraulic fluid from the chamber (3), in order to calibrate the amount of fluid, and the membrane is self-sealing to seal the hole which is formed in the membrane by the penetrating injection needle. The implant typically is a hydraulic constriction device (14), which can be designed for treating reflux disease, urinary incontinence, impotence, anal incontinence or obesity.

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IMPLANTABLE PUMP FOR OPERATION OF HYDRAULIC IMPLANT

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1 The present invention relates to an implantable pump
for pumping hydraulic fluid to or from a hydraulically
5 operable surgical implant inside a human's or an animal's
body. The pump comprises a wall forming a chamber for the
hydraulic fluid, the wall including a first wall portion and
a second wall portion, which is displaceable relative to the
first wall portion to change the volume of the chamber to
10 pump the hydraulic fluid between the chamber and the surgical
implant.

Such an implantable pump is disclosed in US Patent No.
4982731 and is hydraulically connected to an inflatable cuff
forming an annular band around the penis of an impotent
15 patient. This prior art pump includes a squeezable relatively
large reservoir in the form of an elastomeric bladder for
hydraulic fluid. The reservoir is implanted in the patient's
scrotum, so that the patient is enabled to enhance erection
by finger-depressing the squeezable reservoir a number of
20 times to cause the cuff to restrict venous drainage.

An object of the present invention is to provide an
implantable pump, which is thinner and smaller than that of
the prior art, and, therefore, more easily implanted
subcutaneously. Another object of the present invention is
25 to provide an implantable pump, which is more versatile than
that of the prior art. A further object of the present
invention is to provide an implantable pump that is easy to
calibrate.

Accordingly, in accordance with a first aspect of the
30 present invention, there is provided a new implantable pump
of the type presented initially characterized in that the
second wall portion includes a displaceable membrane that is
penetrable by an injection needle to add hydraulic fluid to
or withdraw hydraulic fluid from the chamber, and that the

membrane is self-sealing to seal the hole which is formed in the membrane by the penetrating injection needle. As a result, the amount of hydraulic fluid pumped by the pump can be easily calibrated even when the pump has been subcutaneously implanted in a patient. Thus, the injection needle of a syringe can readily penetrate the patient's skin in front of the membrane and further penetrate the membrane of the pump, so that hydraulic fluid can be added to or removed from the pump chamber from outside the patient's body.

In accordance with a most simple embodiment, the membrane is manually displaceable, i.e. by pushing with a finger the patient's skin in front of the membrane of the subcutaneously implanted pump. In accordance with an alternative the membrane may be magnetically displaceable. Thus, the membrane can be made of a magnetic material or be provided with magnetic elements, and an external permanent magnet or solenoid can be used for repelling and pulling the membrane. In accordance with another alternative, the pump may comprise a motor, which may be remote controlled, adapted to displace the membrane.

Specifically, the membrane is displaceable relative to the first wall portion between a first position, in which the chamber has a first volume, and a second position, in which the chamber has a second volume smaller than the first volume. The membrane preferably is flexible and takes the shape of a semi-sphere, when it is in the first position. Accordingly, when the membrane is displaced to its second position the chamber is substantially emptied and the membrane is in a state of tension.

The implantable pump may further comprise a locking device adapted to releasably lock the membrane in the second position. Thus, the membrane can be displaced from the first position to the second position by manually depressing the

membrane. Moreover, the locking device can be adapted to release the membrane from the second position upon pushing the membrane, and the membrane can be adapted to resume its semi-spherical shape in the first position, when it is released from the second position.

In accordance with a preferred embodiment of implantable pump, the membrane includes a first layer and a second layer attached to each other, the first layer having better strength properties than the second layer and the second layer having better sealing properties than the first layer. As a result, the thickness of the membrane can be very small, i.e. about 3 mm. Thus, the pump of the present invention can be designed relatively thin, which facilitates subcutaneous implantation of the pump.

The membrane layers may be made of silicone, wherein the first silicone layer is harder than the second silicone layer. The second silicone layer suitably has a hardness less than 20 Shore. Generally, the second layer is situated between the first layer and the chamber of the injection port. Alternatively, the membrane may comprise a third layer harder than the second layer, wherein the third layer is situated between the second layer and the chamber. The silicone membrane is mounted under tension, which makes it possible to inject a specific type of hypodermic needle into the fluid chamber of the pump, without causing leakage through the membrane after the needle has been removed from the membrane. This type of hypodermic needle has a lateral opening and does not cut out any remaining hole in the silicone membrane. The needle just moves the silicone material aside.

In accordance with a second aspect of the present invention, there is provided an apparatus for treating a disease, comprising a hydraulically operable surgical

implant, and the implantable pump of the invention for pumping hydraulic fluid to or from the surgical implant.

Generally, the surgical implant comprises a hydraulic constriction device for constricting a passageway of an organ of a human or an animal. The constriction device may be used for constricting the stomach of an obese patient to restrict the patient's food intake, for constricting the esophagus of a patient who suffers from reflux disease, or for restricting the exit penile blood of an impotent patient. Alternatively, the constriction device may be used as an artificial sphincter in an anal or urinary incontinent patient.

In accordance with an embodiment of the apparatus of the invention, the constriction device comprises an inflatable cavity, which is in fluid communication with the chamber of the pump. The cavity is adapted to constrict the passageway when it is inflated and to release the passageway when it is deflated.

In accordance with another embodiment of the apparatus of the invention, the constriction device comprises a relatively small first inflatable cavity, which is in fluid communication with the chamber of the pump, and a relatively large second cavity, which is displaceable by the first cavity. The first cavity is adapted to displace the second cavity to constrict the passageway when the first cavity is inflated and to displace the second cavity to release the passageway when the first cavity is deflated. The second cavity may also be inflatable by fluid. In this case, the apparatus suitably comprises an injection port, which is in fluid communication with the second cavity. As a result, the volume of the second cavity can be calibrated by adding fluid to or withdrawing fluid from the injection port.

Advantageously, the surgical implant and pump of the apparatus are connected to form an operable pump assembly, which is easy to implant in the patient. An operation device

may operate the pump assembly and an implantable motor may drive the operation device. The motor and or other energy consuming parts of the pump assembly may be designed to be powered by wireless energy emitted outside the patient's body.

The apparatus suitably comprises an energy transmission device for wireless transmission of energy from outside the patient's body to inside the patient's body for use in connection with the operation of the pump assembly. The energy transmission device transmits energy of a first form and the pump assembly is operable in response to energy of a second form. The apparatus further comprises an energy transforming device implantable in the patient for transforming the energy of the first form wirelessly transmitted by the energy transmission device into the energy of the second form, which is different than the energy of the first form.

The energy transforming device may include at least one element having a positive region and a negative region, wherein the element is capable of creating an energy field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission device, and the energy field produces the energy of the second form. For example, the element may include an electrical junction element capable of inducing an electric field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission device, whereby the energy of the second form comprises electric energy.

The energy transforming device may be adapted to transform the energy of the first form directly or indirectly into the energy of the second form, wherein the motor is powered by the energy of the second form. The pump assembly may be operable to perform a reversible function and the

motor may be capable of reversing the function. For example, the control device may be adapted to shift polarity of the energy of the second form to reverse the motor. Preferably, the energy transforming device is adapted to directly power the motor by the transformed energy, as the energy of the second form is being transformed from the energy of the first form.

The wireless energy of the first form may include sound waves and the energy of the second form may include electric energy.

In accordance with an embodiment of the invention, the apparatus includes an energy storage device implantable in the patient for storing the energy of the second form and for supplying energy in connection with the operation of the pump assembly. For example, the energy storage device may include an accumulator, such as at least one capacitor or at least one rechargeable battery, or a combination of at least one capacitor and at least one rechargeable battery.

In accordance with another embodiment of the invention, the apparatus includes a source of energy implantable in the patient for supplying energy for the operation of the pump assembly, and a switch operable by the energy of the second form supplied by the energy transforming device to switch from an off mode, in which the source of energy is not in use, to an on mode, in which the source of energy supplies energy for the operation of the pump assembly.

The apparatus may include an implantable stabiliser for stabilising the energy of the second form. Where the energy of the second form includes electric current, the stabiliser includes at least one capacitor.

The apparatus may include implantable electrical components, which may be at least one voltage level guard.

Preferably, the energy transmission device is adapted to transmit wireless energy for direct use in connection with

the operation of the pump assembly, as the wireless energy is being transmitted. The wireless energy may be in the form of a magnetic field or electromagnetic waves for direct power of the pump assembly. The energy transforming device may
5 directly operate the pump assembly with the energy of the second form in a non-magnetic, non-thermal or non-mechanical manner.

The energy transforming device suitably includes at least one semiconductor type of component. The semiconductor
10 component may include at least one element having a positive region and a negative region, wherein the element is capable of creating an energy field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission device, and the energy
15 field produces the energy of the second form.

The pump assembly may be operable to perform a reversible function and a reversing device may be implantable in the patient to reverse the function performed by the pump assembly. The control device suitably controls the reversing
20 device to reverse the function performed by the pump assembly. The reversing device may include hydraulic means including a for shifting the flow direction of a liquid flow in the hydraulic means. Alternatively, the reversing device may include a mechanical reversing device, such as a switch.

25 Preferably, the energy transmission device transmits energy by at least one wireless wave signal, such as an electromagnetic wave signal including one of an infrared light signal, a visible light signal, an ultra violet light signal, a laser signal, a micro wave signal, a radio wave
30 signal, an x-ray radiation signal, and a gamma radiation signal. Alternatively, the wave signal may include a sound or ultrasound wave signal. Any one of these signal types may include a digital or analog signal, or a combination of a digital and analog signal.

The energy of the first form transmitted by the energy transmission device may include an electric, an electromagnetic or a magnetic field, or a combination thereof, which may be transmitted in pulses or digital pulses, or a combination of pulses and digital pulses by the energy transmission device. The energy transforming device suitably transforms the energy of the first form into a direct current or pulsating direct current, or a combination of a direct current and pulsating direct current.

Alternatively, the energy transforming device may transform the energy of the first form into an alternating current or a combination of a direct and alternating current.

One of the energy of the first form and the energy of the second form may include magnetic energy, kinetic energy, sound energy, chemical energy, radiant energy, electromagnetic energy, photo energy, nuclear energy or thermal energy. Also, one of the energy of the first form and the energy of the second form may be non-magnetic, non-kinetic, non-chemical, non-sonic, non-nuclear or non-thermal.

Optionally, the energy transmission device may function differently from or similar to the energy transforming device.

The energy transforming device is suitably designed to be implanted subcutaneously or in the abdomen, thorax or cephalic region of the patient. Alternatively, the energy transforming device may be designed to be implanted in an orifice of the patient's body and under the mucosa or intraluminal outside the mucosa of the orifice.

Advantageously, the apparatus of the invention includes a control device, for example a microprocessor, for controlling the pump assembly. Preferably, the control device includes a remote control, conveniently a wireless remote control, for controlling the pump assembly from outside the patient's body. The wireless remote control may include at

least one external signal transmitter or transceiver and at least one internal signal receiver or transceiver implantable in the patient. The wireless remote control may be adapted to transmit at least one wireless control signal, which may be a frequency, amplitude or frequency or amplitude modulated signal. The control signal may be an analog or a digital signal, or a combination of an analog and digital signal and the remote control may transmit an electromagnetic carrier wave signal for carrying the digital or analog control signal.

The control signal may be a wave signal including one of a sound wave signal, an ultrasound wave signal, an electromagnetic wave signal, an infrared light signal, a visible light signal, an ultra violet light signal, a laser light signal, a micro wave signal, a radio wave signal, an x-ray radiation signal and a gamma radiation signal. The remote control may transmit a carrier signal for carrying the control signal. The carrier signal may include digital, analog or a combination of digital and analog signals. Alternatively, the control signal may include an electric or magnetic field, or a combined electric and magnetic field.

The apparatus may include at least one sensor adapted to be implanted in the patient. The sensor may be adapted to sense at least one physical parameter of the patient and/or at least one functional parameter of a medical implant. Suitably, the control device may control the pump assembly in response to signals from the sensor. The control device may include an implantable internal control unit that directly controls the pump assembly or an external control unit outside the patient's body that controls the pump assembly in response to signals from the sensor.

The apparatus of the invention may include an external data communicator and an implantable internal data communicator communicating with the external data

communicator, wherein the internal communicator feeds data related to the pump assembly back to the external data communicator or the external data communicator feeds data to the internal data communicator.

5 The apparatus of the present invention may be used for any application that requires a small pump injection port system. It may be used for different kinds of implantable hydraulic constriction devices, such as adjustable bands for treating reflux-disease, obesity, urinary incontinence, anal
10 incontinence, and impotence. It may also be used with hydraulic penal implants, as well as with infusion-pumps for drug delivery, etc. .

 The pump assembly may be used for distributing liquid from one part to another part of a human body.

15 The apparatus of the invention may also be used in connection with hydraulically controlled implants to distribute liquid within the hydraulic implant or to distribute liquid to and from an implanted liquid reservoir of the implant. Examples of such hydraulically controlled
20 implants are artificial spincters for occluding a body opening for treating anal incontinence, colostomy, ileostomy, jejunostomy, urine incontinence, or hernia in the cardia region. Another example is a hydraulic constriction device for forming a stoma opening in any part of the body for
25 example in the stomach or esophagus of an obese patient to treat obesity.

 With regard to anal incontinence, colostomy, ileostomy or jejunostomi, the apparatus of the invention may be used for controlling a hydraulic implant as well as, in a large
30 version of the pump assembly of the apparatus, for pumping fecal matter, which may be discharged through a stomy opening and or through the patient's normal anal canal.

The apparatus of the invention may also be used for treating the vascular system, such as restricting or compressing any part of the vascular system

In accordance with a third aspect of the present invention, there is provided a method of operating a hydraulically operable surgical implant implanted in a human or an animal, the method comprising subcutaneously implanting in the human or animal a pump having an injection membrane, which is displaceable to change the volume of a hydraulic fluid chamber in the pump; hydraulically connecting the hydraulic fluid chamber via a conduit to the hydraulically operable surgical implant to form a closed hydraulic fluid distribution system including the fluid chamber, conduit and surgical implant; calibrating the amount of hydraulic fluid in the fluid distribution system by penetrating the patient's skin and the membrane of the implanted pump with an injection needle and adding hydraulic fluid to or withdrawing hydraulic fluid from the fluid chamber; and from time to time, operating the surgical implant by displacing the injection membrane of the subcutaneously implanted pump, so that hydraulic fluid is distributed between the fluid chamber of the pump and the surgical implant.

The method may further comprise operating the surgical implant by manually or magnetically displacing the injection membrane, or, alternatively, by displacing the injection membrane with the aid of a motor.

The present invention also provides a surgical method for treating a patient having a disease, comprising the steps of: insufflating the patient's abdomen with gas; placing at least two laparoscopical trocars in the patient's body; inserting at least one dissecting tool through the trocars and dissecting a region of the patient; implanting a hydraulic surgical implant designed for treating reflux disease, urinary incontinence, impotence, anal incontinence

or obesity, in the dissected area by using surgical instruments through the trocars; subcutaneously implanting in the patient a pump having an injection membrane, which is displaceable to change the volume of a hydraulic fluid chamber in the pump; hydraulically connecting the fluid chamber of the pump to the hydraulic surgical implant; calibrating the amount of fluid in the fluid chamber of the pump by penetrating the patient's skin and the membrane of the pump with an injection needle and adding fluid to or withdrawing fluid from the fluid chamber; and from time to time, operating the surgical implant by manually displacing the injection membrane of the subcutaneously implanted pump, so that hydraulic fluid is distributed between the fluid chamber of the pump and the surgical implant.

The above described methods may also be used for treating reflux disease, urine incontinence, impotence, anal incontinence or obesity or the like.

A preferred embodiment of the present invention will now be described by way of example, with reference to the attached drawings, in which

Figure 1 shows an implantable pump according to the present invention,

Figure 2 and 3 illustrate how the pump shown in Figure 1 is manually operated,

Figure 4 shows an embodiment of an apparatus according to the present invention including the implantable pump shown in Figure 1,

Figure 5 shows another embodiment of the apparatus of the invention,

Figures 6 and 7 show details of the embodiment shown in Figure 5,

Figure 8 shows an alternative design of the embodiment shown in Figure 5, and

Figure 9 shows another embodiment of the apparatus of the invention with a motor-driven pump.

Referring to the drawing figures, like reference numerals designate identical or corresponding elements throughout the several figures.

Figure 1 shows an implantable pump 1 according to the present invention including a wall 2 forming a chamber 3 for hydraulic fluid, typically an isotonic salt solution. A nipple 3A for connection to a tube (not shown) for distributing hydraulic fluid from chamber 3 is provided. The wall 2 includes a first wall portion in the form of a rigid base plate 4 and a second wall portion in the form of a relatively thin flexible injection membrane 5, which takes the shape of a semi-sphere and is attached to base plate 4. The injection membrane 5 enables calibration of the pumpable amount of hydraulic fluid by injecting a hypodermic needle through the membrane 5 and adding hydraulic fluid to or withdrawing hydraulic fluid from chamber 3.

Membrane 5 comprises three layers attached to each other: an external first hard layer 6 having preferably a hardness of more than 20 Shore; a central second soft layer 7 having a hardness of less than 20 Shore; and an internal third hard layer 8, having a hardness suitably more than 20 Shore, but preferably about 60 Shore or more. Soft layer 7 has good sealing properties, which means that as soon as an injection needle has been removed from membrane 5 soft layer 7 automatically seals the hole which was created through membrane 5 by the injection needle, when the latter penetrated membrane 5. The strength property of hard layers 6 and 8, and the sealing properties of soft layer 7 enable membrane 5 to be designed particularly thin. Membrane layers 6, 7 and 8 are suitably made of plastic or silicone, preferably of silicone. Suitable silicon materials are manufactured by "Applied Silicone, Inc."

In most applications of the pump of the present invention it is sufficient if membrane 5 comprises only two layers, i.e. the external hard layer 6 and the soft layer 7. Thus, hard layer 7 has better strength properties than soft layer 7, and soft layer 7 has better sealing properties than hard layer 6.

Figures 2 and 3 illustrate how pump 1 is manually operated. Since central layer 7 of membrane 5 is very soft, i.e. elastic silicone material of less than 20 Shore, it is possible to design a thin and elastic membrane 5, which allows pumping by hand and yet does not cause leakage when a hypodermic needle penetrates membrane 5. As illustrated in Figure 2, with pump 1 subcutaneously implanted in a patient, via the patient's skin 9 a finger 10 can push (actuated by one push) membrane 5 in a direction 11 from above. Membrane 5 will then be substantially flattened, such that the surface of membrane 5 that is faced against finger 10 will assume a somewhat concave bowl-shape 12, see Figure 3. When membrane 5 has been moved to a lowest position a locking device 13 holds it there until it is manually pressed again. When membrane 5 is actuated again, by a second push by finger 10, locking device 13 (which may function similar to the locking mechanism for a ballpoint pen or the like) releases membrane 5, whereby membrane 5 is able to return to its regular convex-shaped state as shown in Figure 2.

Figure 4 shows an embodiment of the apparatus of the invention comprising a surgical implant in the form of a hydraulic constriction device 14, the pump 1 of the invention and a tube 15 hydraulically connecting constriction device 14 and pump 1. Constriction device 14 includes an inflatable cavity 16, which is in fluid communication with chamber 3 of pump 5 via tube 15. Thus, the apparatus has a closed hydraulic distribution system including fluid chamber 3, tube 15 and cavity 16.

Constriction device 14 is for restricting a passageway of an organ of a human or an animal. For example, it may be used as an artificial sphincter applied on the urethra of an incontinent patient. The incontinent patient may push
5 membrane 5 of pump 1 to its locked position, in order to inflate cavity 16 to close the urethra and when needed push membrane 5 to release it, so that cavity 16 is deflated and allows the patient to urinate.

The amount of fluid in the fluid distribution system of
10 the apparatus can be calibrated by penetrating membrane 5 of pump 1 with a needle 17 of a syringe 18 and adding hydraulic fluid to or withdrawing hydraulic fluid from chamber 3 of pump 1.

The apparatus shown in Figure 4 may also be used for
15 treating patients suffering from heartburn and reflux disease, obesity or anal incontinence, or for temporarily restricting the penile exit blood flow of an impotent patient. Thus, in a broad sense, after pump 1 has been subcutaneously implanted in a patient, displaceable injection
20 membrane 5 is used to manually pump hydraulic fluid between fluid chamber 3 and implanted constriction device 14. The total amount of hydraulic fluid in fluid chamber 3, tube 15 and cavity 16 is calibrated by penetrating the patient's skin and membrane 5 with injection needle 17 of syringe 18 to add
25 or withdraw fluid from chamber 5. Membrane 5 is manually displaced from time to time to pump the fluid to or from chamber 3 of pump 1 to operate constriction device 14.

Figure 5 schematically shows another embodiment of the apparatus of the invention, which is similar to the
30 embodiment shown in Figure 4, except that the constriction device is designed differently. Thus, the apparatus according to Figure 5 has a constriction device 19 including a relatively small inflatable cavity 20, which is in fluid communication with chamber 3 of pump 1, and a relatively

large cavity 21, which is displaceable by small cavity 20. Small cavity 20 is adapted to displace large cavity 21 to constrict the passageway when small cavity 20 is inflated and to displace large cavity 21 to release the passageway when
5 small cavity 20 is deflated. Thus, a relatively small addition of hydraulic fluid from pump 1 to small cavity 20 causes a relatively large increase in the constriction of the passageway in question.

Large cavity 21 is defined by a big balloon 22, which
10 is connected to an injection port 23 via a tube 24. Adding fluid to or withdrawing fluid from injection port 23 with the aid of syringe 18 calibrates the volume of balloon 22. Small cavity 20 is defined by a small bellow 25, which at one end is attached to an annular frame 26 of constriction device 19
15 and at the opposite end is attached to balloon 22.

Figures 6 and 7 schematically illustrate the operation of constriction device 19. Referring to Figure 6, when small cavity 20 is deflated bellow 25 pulls balloon 22 inwardly into annular frame 26, so that constriction device 19
20 constricts the passageway in question. Referring to Figure 7, when small cavity 20 is inflated bellow 25 pulls balloon 22 out of annular frame 26, so that constriction device 19 releases the passageway.

Figure 8 shows an alternative design of the apparatus
25 shown in Figure 5. Thus, in this alternative design injection port 23 is substantially smaller than pump 1 and is attached to nipple 3A of pump 1.

Figure 9 shows an embodiment of the apparatus of the invention, which differs from the above-described embodiments
30 in that pump 1 is motor driven. Thus, an electric motor 27 for displacing membrane 5 is placed in chamber 3 on base plate 4. A thread 28 is connected between the top portion of membrane 5 and a pulley 29 on a motor axle of motor 27. When motor 27 is activated it winds thread 28 on pulley 29, so

that membrane 5 is pulled towards base plate 4. When motor 27 is reversed membrane 5 resumes its semi-spherical shape. Motor 27 is powered by wireless energy transmitted from a control device 30 from outside the patient's skin 9. The
5 wireless energy is transformed into electric energy by a wireless energy transforming device 31 electrically connected to motor 27. Control device 30 controls motor 27.

Although the present invention has been described in terms of particular embodiments, it is not intended that the
10 invention be limited to those embodiments. Modifications of the embodiments within the spirit of the invention will be apparent to those skilled in the art. The scope of the invention is defined by the claims that follow.

CLAIMS

1. An implantable pump (1) for pumping hydraulic fluid to or from a hydraulically operable surgical implant (14;19) inside a human's or an animal's body, the pump comprising a wall (2) forming a chamber (3) for the hydraulic fluid, the wall including a first wall portion (4) and a second wall portion (5), which is displaceable relative to the first wall portion to change the volume of the chamber (3) to pump the hydraulic fluid between the chamber and the surgical implant, characterized in that the second wall portion includes a displaceable membrane (5) that is penetrable by an injection needle (17) to add hydraulic fluid to or withdraw hydraulic fluid from the chamber (3), and that the membrane is self-sealing to seal the hole which is formed in the membrane by the penetrating injection needle.

2. An implantable pump according to claim 1, wherein the membrane (5) is manually displaceable.

20

3. An implantable pump according to claim 1 or 2, wherein the membrane (5) is displaceable relative to the first wall portion (4) between a first position (Fig. 2), in which the chamber (3) has a first volume, and a second position (Fig. 3), in which the chamber has a second volume smaller than the first volume.

25

4. An implantable pump according to claim 3, wherein the membrane (5) is flexible and takes the shape of a semi-sphere, when it is in the first position.

30

5. An implantable pump according to claim 4, further comprising a locking device (13) adapted to releasably lock the membrane (5) in the second position.

6. An implantable pump according to claim 5, wherein the locking device (13) is adapted to lock the membrane (5) in the second position, when the membrane is manually pushed
5 from the first position to the second position.

7. An implantable pump according to claim 6, wherein the locking device (13) is adapted to release the membrane (5) from the second position upon pushing the membrane, and
10 the membrane is adapted to resume its semi-spherical shape in the first position, when it is released from the second position.

8. An implantable pump according to any one of claims
15 4-7, wherein the chamber (3) is substantially emptied, when the membrane (5) is in the second position.

9. An implantable pump according to any one of claims 1-8, wherein the membrane (5) includes a first layer (6) and
20 a second layer (7) attached to each other, the first layer (6) having better strength properties than the second layer and the second layer (7) having better sealing properties than the first layer.

25 10. An implantable pump according to claim 9, wherein the first layer (6) is harder than the second layer (7).

11. An implantable pump according to claim 10, wherein the second layer (7) is situated between the first layer (6)
30 and the chamber (3).

12. An implantable pump according to claim 11, wherein the membrane (5) comprises a third layer (8) harder than the

second layer (7), the third layer being situated between the second layer (7) and the chamber (3).

13. An implantable pump according to any one of claims 5 9-12, wherein the second layer (7) is made of silicone having a hardness of less than 20 Shore.

14. Use of an implantable pump according to any one of the preceding claims for pumping hydraulic liquid to and from 10 hydraulic implants designed for treating reflux disease, urine incontinence, impotence, anal incontinence or obesity.

15. An apparatus for treating a disease, comprising a hydraulically operable surgical implant, and an implantable 15 pump (1) for pumping hydraulic fluid to or from the surgical implant (14;19), the pump including a wall (2) forming a chamber (3) for the hydraulic fluid, the wall including a first wall portion (4) and a second wall portion (5), which is displaceable relative to the first wall portion to change 20 the volume of the chamber (3) to pump the hydraulic fluid between the chamber and the surgical implant, characterized in that the second wall portion includes a displaceable membrane (5) that is penetrable by an injection needle (17) to add hydraulic fluid to or withdraw hydraulic fluid from 25 the chamber (3) of the pump (1).

16. An apparatus according to claim 15, wherein the surgical implant comprises a hydraulic constriction device (14;19) for constricting a passageway of an organ of a human 30 or an animal.

17. An apparatus according to claim 16, wherein the constriction device (14) comprises an inflatable cavity (16), which is in fluid communication with the chamber (3) of the

pump (1), and the cavity is adapted to constrict the passageway when it is inflated and to release the passageway when it is deflated.

5 18. An apparatus according to claim 16, wherein the constriction device (19) comprises a relatively small first inflatable cavity (20), which is in fluid communication with the chamber (3) of the pump (1), and a relatively large second cavity (21), which is displaceable by the first
10 cavity, and the first cavity is adapted to displace the second cavity to constrict the passageway when the first cavity is inflated and to displace the second cavity to release the passageway when the first cavity is deflated.

15 19. An apparatus according to claim 18, wherein the second cavity (21) is inflatable by fluid, and further comprising an injection port (23), which is in fluid communication with the second cavity, whereby the volume of the second cavity can be calibrated by adding fluid to or
20 withdrawing fluid from the injection port.

20 20. An apparatus according to any one of claims 15-19, wherein the membrane (5) is manually displaceable.

25 21. An apparatus according to any one of claims 15-20, wherein the membrane (5) is displaceable relative to the first wall portion (4) between a first position (Fig. 2), in which the chamber (3) has a first volume, and a second position (Fig. 3), in which the chamber has a second volume
30 smaller than the first volume.

22. An apparatus according to claim 21, wherein the membrane (5) is elastic and takes the shape of a semi-sphere, when it is in the first position.

23. An apparatus according to claim 22, further comprising a locking device (13) adapted to releasably lock the membrane (5) in the second position.

24. An apparatus according to claim 23, wherein the locking device (13) is adapted to lock the membrane (5) in the second position, when the membrane is manually pushed from the first position to the second position.

25. An apparatus according to claim 24, wherein the locking device (13) is adapted to release the membrane (5) from the second position upon pushing the membrane, whereby the membrane resumes its semi-spherical shape in the first position.

26. An apparatus according to any one of claims 15-25, wherein the chamber (3) is substantially emptied, when the membrane (5) is in the second position.

27. An apparatus according to any one of claims 15-26, wherein the membrane (5) includes a first layer (6) and a second layer (7) attached to each other, the first layer (6) having better strength properties than the second layer and the second layer (7) having better sealing properties than the first layer.

28. An apparatus according to claim 27, wherein the first layer (6) is harder than the second layer (7).

29. An apparatus according to claim 28, wherein the second layer (7) is situated between the first layer (6) and the chamber (3).

30. An apparatus according to claim 29, wherein the membrane (5) comprises a third layer (8) harder than the second layer (7), the third layer being situated between the second layer (7) and the chamber (3).

5

31. An apparatus according to any one of claims 27-30, wherein the second layer (7) is made of silicone having a hardness of less than 20 Shore.

10

32. A method of operating a hydraulically operable surgical implant (14;19) implanted in a human or an animal, the method comprising:

15

subcutaneously implanting in the human or animal a pump (1) having an injection membrane (5), which is displaceable to change the volume of a hydraulic fluid chamber (3) in the pump;

20

hydraulically connecting the hydraulic fluid chamber via a conduit (15) to the hydraulically operable surgical implant to form a closed hydraulic fluid distribution system including the fluid chamber, conduit and surgical implant;

25

calibrating the amount of hydraulic fluid in the fluid distribution system by penetrating the patient's skin (9) and the membrane of the implanted pump with an injection needle (17) and adding hydraulic fluid to or withdrawing hydraulic fluid from the fluid chamber; and

30

from time to time, operating the surgical implant by displacing the injection membrane of the subcutaneously implanted pump, so that hydraulic fluid is distributed between the fluid chamber of the pump and the surgical implant.

33. A method according to claim 32, wherein the surgical implant is operated by manually or magnetically displacing the injection membrane.

34. A method according to claim 32, wherein the surgical implant is operated by displacing the injection membrane with the aid of a motor.

5

35. An implantable pump according to claim 1, 3-13, wherein the membrane (5) is magnetically displaceable.

36. An apparatus according to any one of claims 15-19,
10 21-31, wherein the membrane (5) is magnetically displaceable.

37. An apparatus according to claim 15, wherein the surgical implant and pump are connected to form an operable pump assembly.

15

38. An apparatus according to claim 37, further comprising an implantable operation device adapted to operate the pump assembly.

20 39. An apparatus according to claim 38, further comprising an implantable motor for driving the operation device.

40. An apparatus according to claim 39, wherein the
25 motor is designed to be powered by wireless energy emitted outside the patient's body.

41. An apparatus according to claim 37 further comprising an energy transmission device for wireless
30 transmission of energy from outside the patient's body to inside the patient's body for use in connection with the operation of the pump assembly.

42. An apparatus according to claim 41, wherein the energy transmission device transmits energy of a first form and the pump assembly is operable in response to energy of a second form, and further comprising an energy transforming
5 device implantable in the patient for transforming the energy of the first form wirelessly transmitted by the energy transmission device into the energy of the second form.

43. An apparatus according to claim 42, wherein the
10 energy of the second form is different than the energy of the first form.

44. An apparatus according to claim 42, wherein the energy transforming device comprises at least one element
15 having a positive region and a negative region, the element is capable of creating an energy field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission device, and the energy field produces the energy of the second form.

20 45. An apparatus according to claim 44, wherein the element comprises an electrical junction element, and the electrical junction element is capable of inducing an electric field between the positive and negative regions when
25 exposed to the energy of the first form transmitted by the energy transmission device, whereby the energy of the second form comprises electric energy.

46. An apparatus according to claim 42, wherein the
30 energy transforming device is adapted to transform the energy of the first form directly or indirectly into the energy of the second form.

47. An apparatus according to claim 46, further comprising an implantable motor for operating the pump assembly, wherein the motor is powered by the energy of the second form.

5

48. An apparatus according to claim 47, wherein the pump assembly is operable to perform a reversible function and the motor is capable of reversing the function.

10

49. An apparatus according to claim 47, further comprising a control device adapted to shift polarity of the energy of the second form to reverse the motor.

15

50. An apparatus according to claim 47, wherein the energy transforming device is adapted to directly power the motor by the transformed energy, as the energy of the second form is being transformed from the energy of the first form.

20

51. An apparatus according to claim 46, wherein the wireless energy of the first form comprises sound waves and the energy of the second form comprises electric energy.

25

52. An apparatus according to claim 42, further comprising an energy storage device implantable in the patient for storing the energy of the second form and for supplying energy in connection with the operation of the pump assembly.

30

53. An apparatus according to claim 52, wherein the energy storage device comprises an accumulator.

54. An apparatus according to claim 53, wherein the accumulator comprises at least one capacitor or at least one

rechargeable battery, or a combination of at least one capacitor and at least one rechargeable battery.

55. An apparatus according to claim 42, further
5 comprising a source of energy implantable in the patient for supplying energy for the operation of the pump assembly, and a switch operable by the energy of the second form supplied by the energy transforming device to switch from an off mode, in which the source of energy is not in use, to an on mode,
10 in which the source of energy supplies energy for the operation of the pump assembly.

56. An apparatus according to claim 42, further
comprising an implantable stabiliser for stabilising the
15 energy of the second form.

57. An apparatus according to claim 56, wherein the energy of the second form comprises electric current and the stabiliser comprises at least one capacitor.
20

58. An apparatus according to claim 41, further comprising implantable electrical components including at least one voltage level guard.

25 59. An apparatus according to claim 41, wherein the energy transmission device is adapted to transmit wireless energy for direct use in connection with the operation of the pump assembly, as the wireless energy is being transmitted.

30 60. An apparatus according to claim 41, wherein the energy transmission device is adapted to transmit wireless energy in the form of a magnetic field or electromagnetic waves for direct power of the pump assembly.

61. An apparatus according to claim 42, wherein the energy transforming device directly operates the pump assembly with the energy of the second form in a non-magnetic, non-thermal or non-mechanical manner.

5

62. An apparatus according to claim 42, wherein the energy transforming device comprises at least one semiconductor type of component.

10

63. An apparatus according to claim 62, wherein the semiconductor component comprises at least one element having a positive region and a negative region, the element is capable of creating an energy field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission device, and the energy field produces the energy of the second form.

15

64. An apparatus according to claim 37, wherein the pump assembly is operable to perform a reversible function.

20

65. An apparatus according to claim 64, further comprising a reversing device implantable in the patient for reversing the function performed by the pump assembly.

25

66. An apparatus according to claim 65, wherein the control device controls the reversing device to reverse the function performed by the pump assembly.

67. An apparatus according to claim 65, wherein the reversing device comprises hydraulic means including a for shifting the flow direction of a liquid flow in the hydraulic means.

30

68. An apparatus according to claim 65, wherein the reversing device comprises a mechanical reversing device.

69. An apparatus according to claim 65, wherein the
5 reversing device comprises a switch.

70. An apparatus according to claim 41, wherein the energy transmission device transmits energy by at least one wireless signal.

10

71. An apparatus according to claim 70, wherein the signal comprises a wave signal.

72. An apparatus according to claim 71, wherein the wave
15 signal comprises an electromagnetic wave signal including one of an infrared light signal, a visible light signal, an ultra violet light signal, a laser signal, a micro wave signal, a radio wave signal, an x-ray radiation signal, and a gamma radiation signal.

20

73. An apparatus according to claim 71, wherein the wave signal comprises a sound or ultrasound wave signal.

74. An apparatus according to claim 70, wherein the
25 signal comprises a digital or analog signal, or a combination of a digital and analog signal.

75. An apparatus according to claim 42, wherein the energy of the first form transmitted by the energy
30 transmission device comprises an electric, an electromagnetic or a magnetic field, or a combination thereof.

76. An apparatus according to claim 75, wherein the electric, electromagnetic or magnetic field, or the

combination thereof is transmitted in pulses or digital pulses, or a combination of pulses and digital pulses by the energy transmission device.

5 77. An apparatus according to claim 42, wherein the energy transforming device transforms the energy of the first form into a direct current or pulsating direct current, or a combination of a direct current and pulsating direct current.

10 78. An apparatus according to claim 42, wherein the energy transforming device transforms the energy of the first form into an alternating current or a combination of a direct and alternating current.

15 79. An apparatus according to claim 42, wherein one of the energy of the first form and the energy of the second form comprises magnetic energy, kinetic energy, sound energy, chemical energy, radiant energy, electromagnetic energy, photo energy, nuclear energy or thermal energy.

20 80. An apparatus according to claim 42, wherein one of the energy of the first form and the energy of the second form is non-magnetic, non-kinetic, non-chemical, non-sonic, non-nuclear or non-thermal.

25 81. An apparatus according to claim 42, wherein the energy transmission device functions different from the energy transforming device.

30 82. An apparatus according to claim 42, wherein the energy transmission device functions similar to the energy transforming device.

83. An apparatus according to claim 42, wherein the energy transforming device is designed to be implanted subcutaneously or in the abdomen, thorax or cephalic region of the patient.

5

84. An apparatus according to claim 42, wherein the energy transforming device is designed to be implanted in an orifice of the patient's body and under the mucosa or intraluminal outside the mucosa of the orifice.

10

85. An apparatus according to claim 15, further comprising at least one sensor adapted to be implanted in the patient.

15

86. An apparatus according to claim 85, wherein the sensor is adapted to sense at least one physical parameter of the patient.

20

87. An apparatus according to claim 85, wherein the sensor is adapted to sense at least one functional parameter of a medical implant.

25

88. An apparatus according to claim 85, further comprising a control device for controlling the surgical implant and pump in response to signals from the sensor.

30

89. An apparatus according to claim 88, wherein the control device comprises an implantable internal control unit that directly controls the surgical implant and pump in response to signals from the sensor.

90. An apparatus according to claim 88, wherein the control device comprises an external control unit outside the

patient's body for controlling the surgical implant and pump in response to signals from the sensor.

91. An apparatus according to claim 37, further
5 comprising a control device for controlling the pump assembly.

92. An apparatus according to claim 91, wherein the control device comprises a remote control for controlling the
10 pump assembly from outside the patient's body.

93. An apparatus according to claim 92, wherein the remote control comprises a wireless remote control.

15 94. An apparatus according to claim 93, wherein the wireless remote control is adapted to transmit at least one wireless control signal for controlling the pump assembly.

95. An apparatus according to claim 95, wherein the
20 control signal comprises a frequency, amplitude or frequency or amplitude modulated signal.

96. An apparatus according to claim 94, wherein the control signal comprises an analog or a digital signal, or a
25 combination of an analog and digital signal.

97. An apparatus according to claim 91, wherein the control device comprises a microprocessor.

30 98. An apparatus according to claim 93, wherein the wireless remote control comprises at least one external signal transmitter or transceiver and at least one internal signal receiver or transceiver implantable in the patient.

99. An apparatus according to claim 94, wherein the remote control transmits a carrier signal for carrying the control signal.

5 100. An apparatus according to claim 99, wherein the carrier signal comprises digital, analog or a combination of digital and analog signals.

10 101. An apparatus according to claim 100, wherein the signals comprise wave signals.

15 102. An apparatus according to claim 94, wherein the control signal comprises a wave signal comprising one of a sound wave signal, an ultrasound wave signal, an electromagnetic wave signal, an infrared light signal, a visible light signal, an ultra violet light signal, a laser light signal, a micro wave signal, a radio wave signal, an x-ray radiation signal and a gamma radiation signal.

20 103. An apparatus according to claim 94, wherein the control signal comprises an electric or magnetic field, or a combined electric and magnetic field.

25 104. An apparatus according to claim 96, wherein the remote control transmits an electromagnetic carrier wave signal for carrying the digital or analog control signal.

30 105. An apparatus according to claim 37, further comprising an external data communicator and an implantable internal data communicator communicating with the external data communicator, wherein the internal communicator feeds data related to the pump assembly back to the external data communicator or the external data communicator feeds data to the internal data communicator.

106. A pump according to claim 1, further comprising an operation device adapted to operate the membrane.

5 107. A pump according to claim 106, further comprising a motor for driving the operation device.

108. A pump according to claim 107, wherein the pump is adapted for implantation in a human body and the motor is
10 adapted to be controlled by a remote control outside the human body.

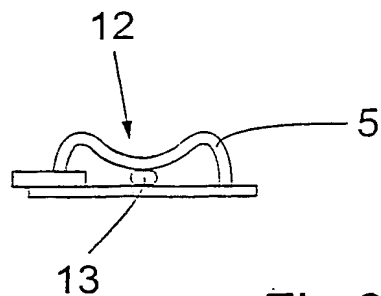
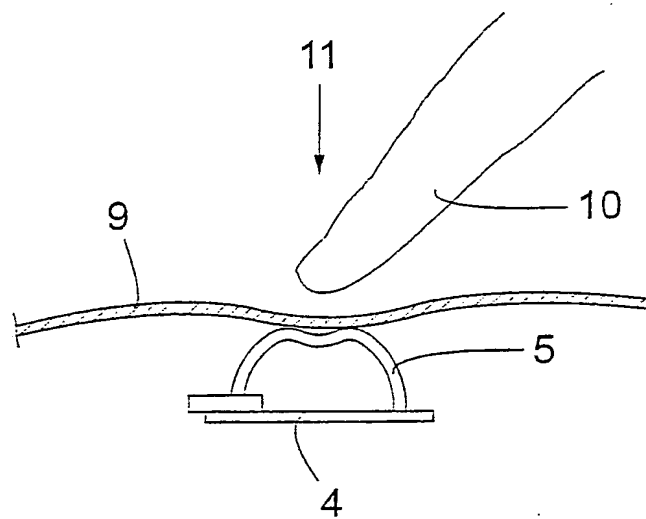
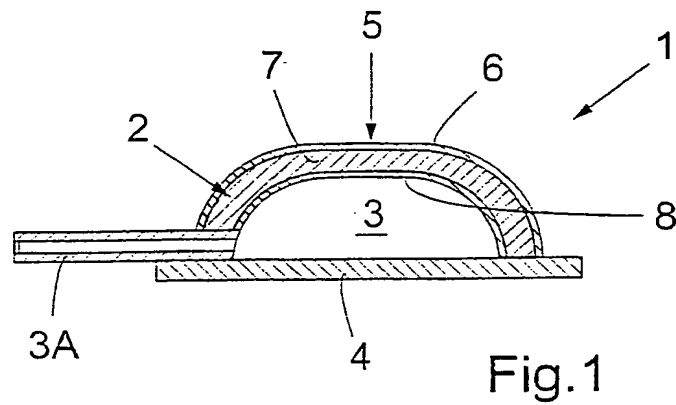
109. A pump according to claim 107, wherein the pump is adapted for implantation in a human body and the motor is
15 designed to be powered by wireless energy emitted outside the human body.

110. A pump according to claim 106, wherein the pump is adapted for implantation in a human body and further
20 comprising a control device for controlling the operation device.

111. A pump according to claim 110, wherein the control device comprises a remote control for controlling the
25 operation device from outside the human body.

112. A pump according to claim 106, further comprising a magnet for driving the operation device.

30 113. A pump according to claim 112, wherein the pump is adapted for implantation in a human or animal and the magnet is adapted to control the pump from outside the human body.



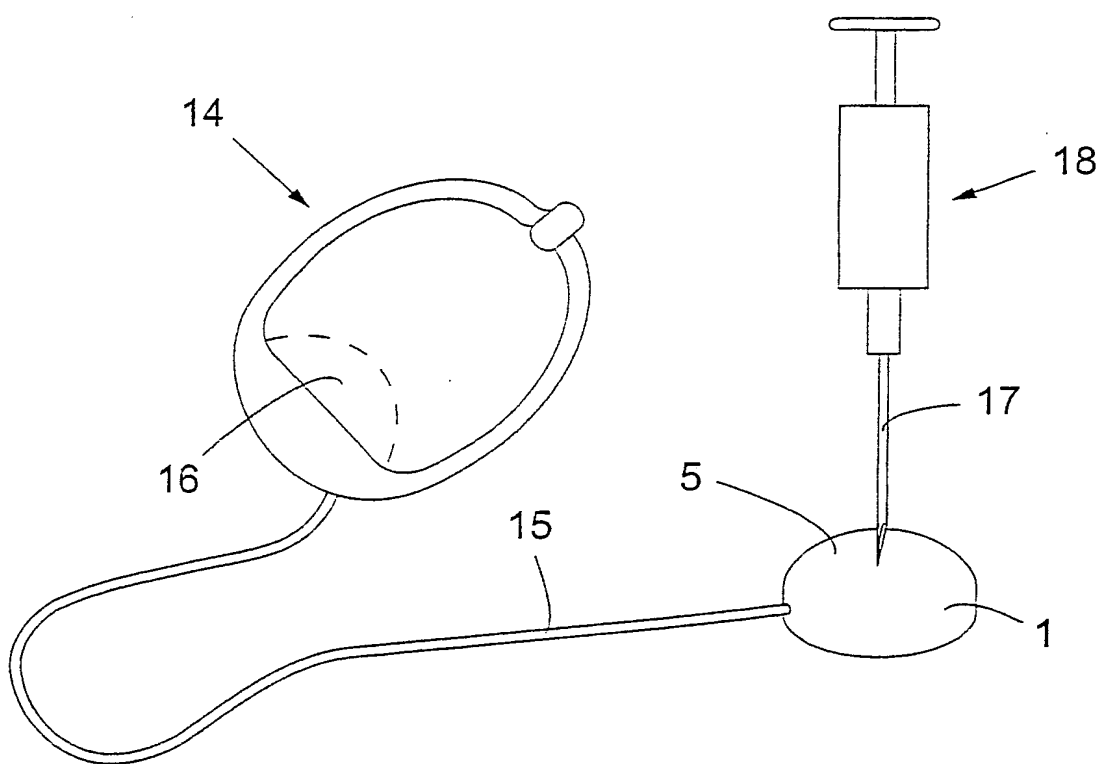


Fig.4

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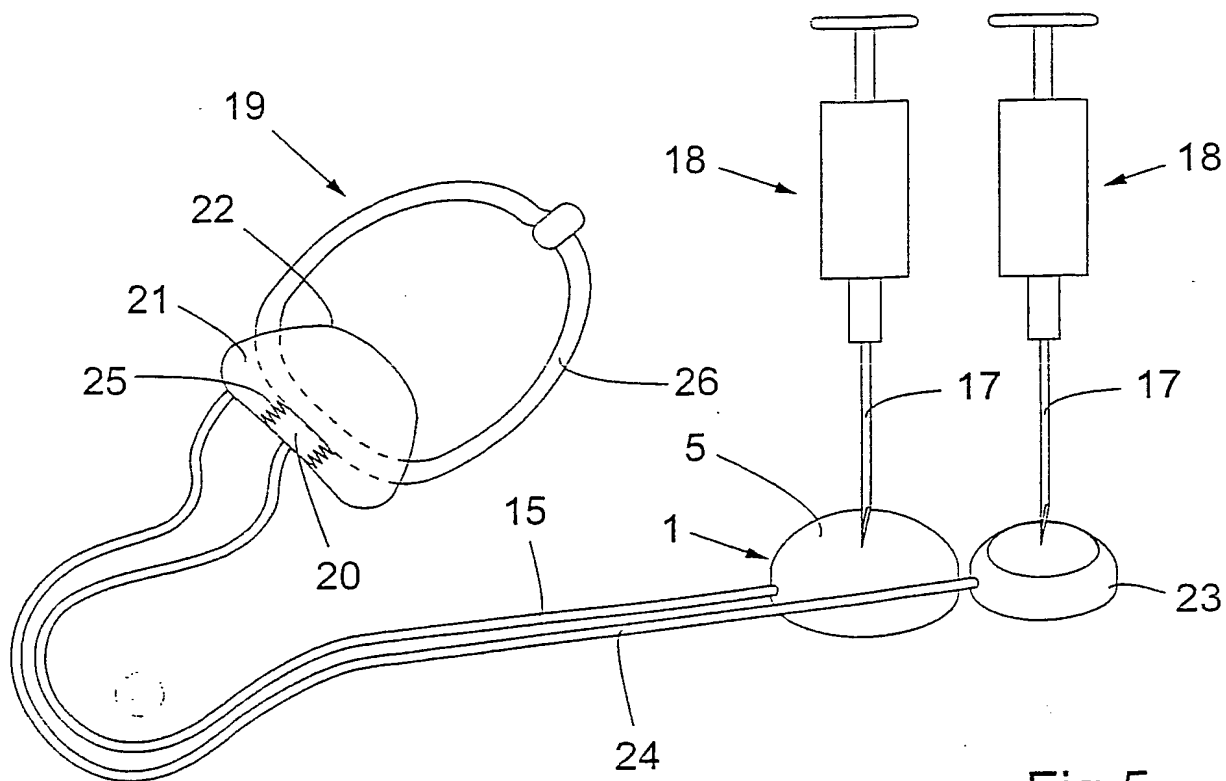


Fig.5

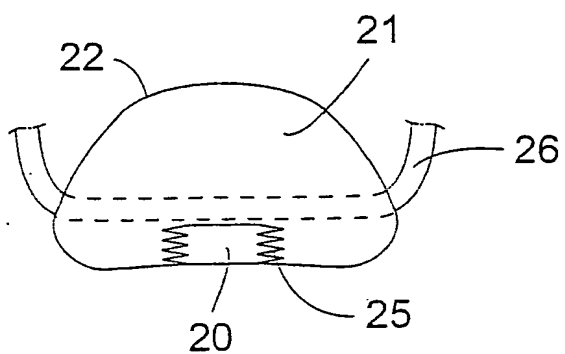


Fig.6

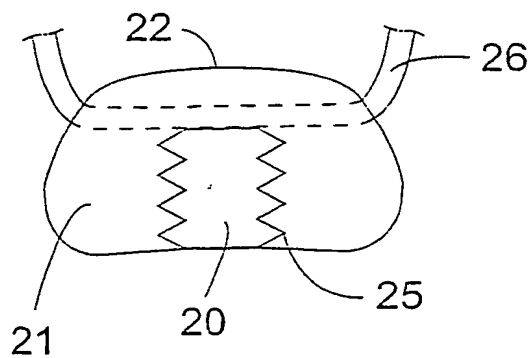


Fig.7

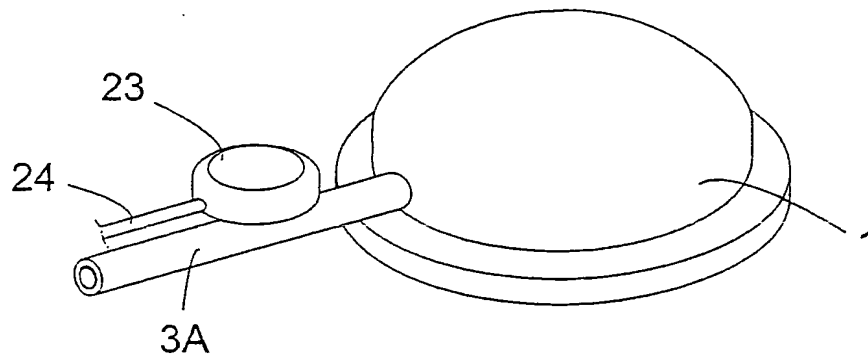


Fig. 8

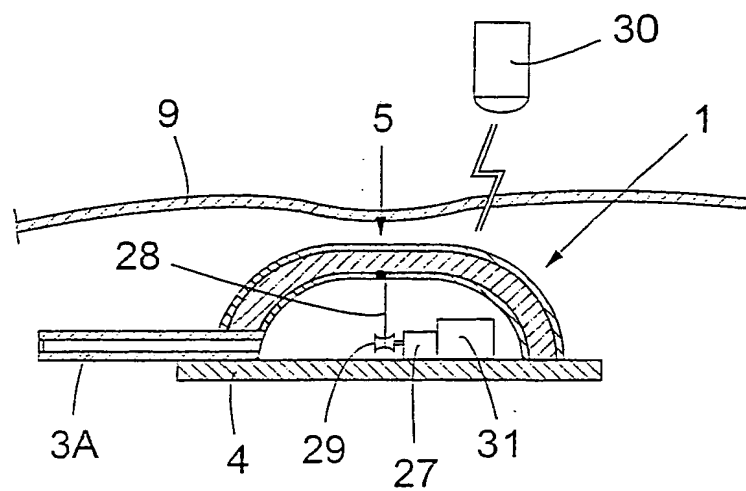


Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/01531

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 39/02, A61F 2/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0532162 A1 (MENTOR CORPORATION), 17 March 1993 (17.03.93), column 8, line 43 - line 49, figure 7, abstract --	1-13,15-31, 35-113
A	US 4190040 A (RUDOLF R. SCHULTE), 26 February 1980 (26.02.80), column 2, line 23 - line 37, figure 3, abstract --	1-13,15-31, 35-113
A	EP 0252258 A1 (FRESENIUS AG), 13 January 1988 (13.01.88), claims 1-7, abstract --	1-3,15-31, 35-113

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

8 December 2003

Date of mailing of the international search report

09-12-2003

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Box 5055, S-102 42 STOCKHOLM

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/01531

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4773403 A (MARK D. DALY), 27 Sept 1988 (27.09.88), column 5, line 41 - line 48, abstract --	1-13,15-31, 35-113
A	WO 0147434 A2 (POTENCIA MEDICAL AG), 5 July 2001 (05.07.01), page 25, line 28 - line 31, figures 29-35, abstract -- -----	1-13,15-31, 35-113

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE03/01531

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **14, 32-34**
because they relate to subject matter not required to be searched by this Authority, namely:
See PCT Rule 39.1(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

06/09/03

International application No.

PCT/SE 03/01531

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
EP	0532162	A1	17/03/93	CA	2078099 A	13/03/93
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				CA	2397922 A	05/07/01
				CN	1416328 T	07/05/03
				EP	1253877 A	06/11/02
				US	2003109771 A	12/06/03

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